DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 16, 2014

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K143284
Trade/Device Name: Elecsys Estradiol III CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: November 14, 2014
Received: November 17, 2014

Dear Kelli Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143284

Device Name
Elecsys Estradiol III CalCheck

Indications for Use *(Describe)*
For use in the verification of the calibration established by the Elecsys Estradiol III reagent on the indicated Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary, Elecsys Estradiol III CalCheck

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: December 12, 2014

Device Name

Proprietary name:	Elecsys Estradiol III CalCheck
Common name:	Estradiol III CalCheck
Classification:	Class 1, reserved
	21 CFR 862.1660, Single (specified) analyte controls (assayed and unassayed)
Product Code:	JJX

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Device Description

Elecsys Estradiol III CalCheck:

- The Elecsys Estradiol III CalCheck is a lyophilized product consisting of synthetic Estradiol in a human serum matrix. It has been standardized against CRM6004a via ID-GC/MS (isotope dilution gas chromatography mass spectrometry).

Intended use

Elecsys Estradiol III CalCheck:

- For use in the verification of the calibration established by the Elecsys Estradiol III reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Predicate device

The Elecsys Estradiol III CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys CalCheck Estradiol (k970148).

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Comparison Table The table below compares Elecsys Estradiol III CalCheck with the predicate device, Elecsys CalCheck Estradiol (k970148).

Characteristic	Elecsys Estradiol III CalCheck (Candidate)	Elecsys CalCheck Estradiol (k970148)
Intended Use	For use in the verification of the calibration established by the Elecsys Estradiol III reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys CalCheck Estradiol is for use in the verification of the calibration established by the Elecsys Estradiol reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Estradiol (synthetic)	Same
Matrix	Human serum matrix	Same
Levels	Three	Same
Assay Measuring Range	5 – 3000 pg/mL	5 – 4300 pg/mL
Check Target Values	Check 1: 100 pg/mL Check 2: 1500 pg/mL Check 3: 2400 pg/mL	Check 1: 200 pg/mL Check 2: 2000 pg/mL Check 3: 4000 pg/mL
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, and Check 3with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion to ensure homogeneity.	Reconstitute the contents of Check 1, Check 2 and Check 3 with exactly 1.5 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Opened: • 15-25°C: 4 hours

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Traceability

The Elecsys Estradiol III CalCheck was standardized against CRM6004a via ID-GC/MS (isotope dilution gas chromatography mass spectrometry).

Value Assignment

Value assignment testing was conducted and passed pre-defined acceptance criteria. For each Elecsys Estradiol III CalCheck lot manufactured, the CalChecks are run in duplicate on at least three **cobas e** 601/MODULAR ANALYTICS E170 analyzers. The assigned value of each CalCheck is defined as the mean value obtained over at least 6 determinations (duplicate runs on at least 3 analyzers) of the respective CalCheck.

The CalCheck assigned range is calculated as ±27% of the assigned value for all levels (1, 2 and 3). The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

The same value assignment procedure is performed on the **cobas e** 411/Elecsys 2010. The assigned values obtained are compared to those obtained on the **cobas e** 601. The mean value obtained on the additional analyzer must be within 10% of the master platform assigned value. After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the MODULAR ANALYTICS E170, Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 immunoassay analyzers.

Target Values

The CalCheck target values for the Elecsys Estradiol III are as follows:

Check Target Values	Check 1: 100 pg/mL Check 3: 1500 pg/mL Check 3: 2400 pg/mL

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Stability Studies

Two studies were performed in order to verify the stability claims for the Estradiol III CalCheck. Additionally, a real-time stability study is ongoing to support the shelf-life stability claim.

Opened-vial and accelerated stability studies were completed on the cobas e 411. Because these studies are not analyzer-dependent, these results, in addition to real-time stability study results, can be applied to the Elecsys 2010, MODULAR ANALYTICS E170, cobas e 601 and cobas e 602.

Study 1. Open-Vial Stability:

The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored for 6 hours at 25ºC (in an open vial). The reference material was a freshly reconstituted set of CalChecks. The on-test recovery was calculated as a percent of the reference value.

One Estradiol III CalCheck lot was evaluated in duplicate on the cobas e 411. The acceptance criterion for CalCheck Level 1 is 85-115% recovery; and for CalCheck Levels 2-3, the acceptance criterion is recovery of 90-110% recovery of the reference material value.
The data support the package insert claim that reconstituted Estradiol III CalCheck is stable up to 4 hours at 20-25°C.

The CalCheck products are not stored on-board the analyzers, therefore no on-board stability claims are made.

Study 2. Accelerated Stability:

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was a freshly reconstituted set of CalChecks (stored at 2-8°C). After 3 weeks, the test and reference materials were tested in duplicate. The on-test recovery was calculated as a percent of the reference value.

One Estradiol III CalCheck lot was evaluated in duplicate on the cobas e 411. The acceptance criterion for CalCheck Level 1 is 85-115% recovery; and for CalCheck Levels 2-3, the acceptance criterion is recovery of 90-110% of the reference material value.

The accelerated stability model employed supports an initial shelf-life claim of 18 months when the Estradiol III CalCheck are stored under normal storage conditions of 2-8°C.

Real-time stability studies are ongoing.

Conclusion

We trust that the data and information provided in this Premarket Notification 510(k) submission will support a determination of substantial equivalence for the Elecsys Estradiol III CalCheck.